FEB 2 6 2014

Section 5 510(k) Summary

510(k) Owner:	Arthrosurface, Inc. 28 Forge Parkway Franklin, MA 02038 Tel: 508.520.3003 Fax: 508.528.4604
Contact:	Dawn Wilson VP, Quality & Regulatory
Date of Preparation:	February 21, 2014
Trade Name:	Arthrosurface® ToeMotion™
Common Name:	Arthrosurface® Total Toe – Proximal Phalanx Implant
Device:	Prosthesis, Toe (metatarso-phalangeal), Joint, Metal/polymer, Semi-constrained
Classification Regulation:	Unclassified (Reason: Pre-Amendment)
Device Class:	Unclassified
Review Panel:	Orthopedic
Product Code:	LZJ

Device Intended Use

The Arthrosurface Total Toe Resurfacing System is a two-piece implant that is intended to be used as prosthesis for the metatarso-phalangeal joint (MTP). The device is intended for cemented use only.
Indications for use include:

- Painful degenerative metatarso-phalangeal joint change
- Hallus rigidus stage 3 and 4
- Hallux valgus and hallux rigidus
- Hallux limitus with painful arthrofibrosis
- Revisions after moderate proximal phalanx resection

Device Description

The Arthrosurface® Total Toe System consists of a metatarsal component and a phalangeal component designed for resurfacing the 1st metatarsal head and the base of the proximal phalanx. These two implants replace the metatarso-phalangeal joint by complete functional preservation of the joint and maintaining of the sesamoid complex.

The Metatarsal Implant incorporates a CoCrMo articular resurfacing component per ASTM F799 with CP Ti Plasma Spray coating per ASTM F1580 and a Ti-6Al-4V ELI alloy fixation component per ASTM F136 that mate together via a taper interlock to provide stable and immobile fixation of the implant and stress bearing contact at the bone/prosthetic interface. The device is 15mm articular implant with a dorsal flange feature for additional implant coverage in the dorsal plane.

The Proximal Phalanx Implant consists of a Ti-6Al-4V ELI alloy fixation component per ASTM F136 with CP Ti Plasma Spray coating per ASTM F1580 and an Ultra High Molecular Weight Polyethylene inlay per ASTM F648.

Substantial Equivalency:

The intended use, materials, design features and application of the Proposed Device are substantially equivalent to the following previously cleared and commercially marketed devices:

- Ascension MOVEMENT Great Toe System K102549
- Merete ToeMobile Anatomical Great Toe Resurfacing System K072251

The fundamental scientific technology of the proposed device has not changed relative to the predicate devices.

- Total arthroplasty for the MTP joint
- Same indications for use
- Similar device designs
- Same implant materials

In support of this submission, the following non-clinical tests have been performed on the Subject Device:

- Wear testing
- Contact area / Contact stress
- Assembly / Disassembly of Articular and Fixation components
- Bending moment / Flexural load
- Strength of delivery tool
- Finite Element Analysis

The results have demonstrated the safety and effectiveness of the Arthrosurface® Total Toe – Proximal Phalanx Implant along with substantial equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 26, 2014

Arthrosurface, Incorporated
Ms. Dawn Wilson
Vice President, Quality and Regulatory
28 Forge Parkway
Franklin, Massachusetts 02038

Re: K132496
Trade/Device Name: Arthrosurface® Total Toe – Proximal Phalanx Implant
Regulation Number: Unclassified
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: LZJ
Dated: January 24, 2014
Received: January 28, 2014

Dear Ms. Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known): K132496

Device Name: Arthrosurface® Total Toe – Proximal Phalanx Implant

Indications for Use:

The Arthrosurface Total Toe Resurfacing System is a two-piece implant that is intended to be used as prosthesis for the metatarso-phalangeal joint (MTP). The device is intended for cemented use only. Indications for use include:

- Painful degenerative metatarso-phalangeal joint change
- Hallus rigidus stage 3 and 4
- Hallux valgus and hallux rigidus
- Hallux limitus with painful arthrofibrosis
- Revisions after moderate proximal phalanx resection

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Casey L. Hanley, Ph.D.

Division of Orthopedic Devices